



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

#14

Food and Drug Administration
Rockville MD 20857

FEB 21 1989

Re: Optiray
Docket No. 89E-0055

Charles E. Van Horn, Esq.
Deputy Solicitor, Solicitor's Office
U.S. Patent and Trademark Office
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U.S. Patent No. 4,396,589 filed by Mallinckrodt, Inc. under 35 U.S.C. 156. The human drug product claimed by the patent is Optiray (ioversol), New Drug Application (NDA 19-710).

A review of the Food and Drug Administration's official records confirms that Optiray was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records also indicate that NDA 19-710 represents the first permitted commercial marketing or use of the active ingredient, ioversol. The NDA was approved on December 30, 1988 which makes the submission of the patent term extension application on February 9, 1989 timely within 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C 165(d)(2)(A), we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)

cc: George R. Repper
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